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10/814,362

03/31/2004

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EXAMINER

GEORGE, TARA R

ART UNIT

PAPER NUMBER

3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/814,362 | Applicant(s) BERRY, BRET M. | |
| | Examiner TARA R. GEORGE | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-122 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 76-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs (US 5658337) in view of Ferree (US 2004/0260286).

Kohrs teaches, with respect to claim 76, an artificial implant 100 comprising an upper shell (see fig. 2 and note the portion above the indicated x-axis), at least one elongated projection 30 comprising a first material; a lower shell (see fig. 2 and note the portion below the indicated x-axis); and a plurality of pillars (see fig. 2 and note that 22, 36 and 30a each consist of 2 pillars that are separated by the axis indicated by x- i.e. near 26 and 28 are the pillars at 22) comprising a second material (note that the first and second materials are the same).

Kohrs further teaches, as for claim 77, wherein the lower shell further comprises at least one elongated projection 30 comprising a first portion comprised of a third material (see fig. 2 and note that the tip of 30 is the first portion).

Kohrs further teaches, as for claim 78, wherein the first portion is spaced from the upper surface (see fig. 2 and note that the first portion is the tip of 30 and furthest away from the x-axis).

As for claims 82 and 83, Kohrs teaches that the plurality of pillars and the at least one elongated projection are each comprised of a material, but does not explicitly state that each are a shape memory alloy and superelastic within a temperature range of a live human body. However, it is noted that it would have been obvious to one of ordinary skill in the art at the time of the invention that shape memory alloys exhibit superelasticity within a temperature range of a live human body is common knowledge in the art. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the implant of Kohrs with shape memory alloys, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Kohrs teaches, as for claim 88, wherein each of the plurality of pillars comprises a substantially identical shape (see fig. 2).

As for claims 89-95, Kohrs teaches that at least one of the pillars comprises a first shape and a second shape (see fig. 2), but does not explicitly state that the first and second shapes are different or that one of said shapes comprises a tetrahedron, hour-glass, rectangular prism, pyramid, cone or irregular shape. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shape of at least one of the plurality of pillars to provide the best support. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary

skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Kohrs teaches, as for claim 96, wherein at least one of the pillars comprises a substantially polygonal cross-sectional shape (see fig. 2).

As for claims 97 and 98, Kohrs teaches the claimed invention except for explicitly stating that at least one of the plurality of pillars comprises either a fillet adjacent one of the upper and lower shells; or an upper fillet adjacent the upper shell and a lower fillet adjacent the lower shell. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shape of at least one of the plurality of pillars to provide the best support. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

As for claim 99, Kohrs teaches the claimed invention except for explicitly stating a first cross-sectional area proximate at least one of the upper and lower shells and a second cross-sectional area distal from the upper and lower shells, wherein the first cross-sectional area is substantially greater than the second cross-sectional area. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shape of at least one of the plurality of pillars to provide the best support. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice

which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

As for claims 101 and 102, Kohrs teaches the claimed invention except for explicitly stating that at least one of the pillars has a height to width ratio of less than about 5:1; or between about 1:1 and about 3:1 wherein the height is measured between opposing interior surfaces of the upper and lower shells and the width is a minimum width of the pillar. It would have been obvious to one of ordinary skill in the art would have been led to the recited dimensions through routine experimentation and optimization. Applicant has not disclosed that the dimensions are for a particular unobvious purpose, produce an unexpected result, or are otherwise critical, and it appears prima facie that the process would possess utility using another set of dimensions. Indeed, it has been held that mere dimensional limitations are prima facie obvious absent a disclosure that the limitations are for a particular unobvious purpose, produce an unexpected result, or are otherwise critical. See, for example, *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). See also MPEP 2144.04(IV)(B).

With respect to claims 76-99 and 101-102, Kohrs teaches the claimed invention except for stating that the upper shell elongated projection is comprised of a first shape memory alloy; the pillars are resiliently deformable and comprise a second shape memory alloy; the first postion comprising a third shape memory alloy; a second portion

comprised of a second material that is more rigid than the first memory alloy, and the lower shell elongated projection is comprised of a second portion comprised of a fourth material that is more rigid than the third memory alloy; wherein the second portion extends between the upper surface and the first portion, as per claim 79; wherein the second portion extends substantially perpendicular to the upper surface and the first portion extends obliquely relative to the upper surface, as per claim 80; and wherein the first portion extends at an acute angle relative to the upper surface, as per claim 81.

Ferree teaches using shape memory materials including an elongated projection (refer to the keel- see para. 57) with a first portion 1252 comprised of a shape memory alloy (see para. 57) and a second portion comprised of a more rigid material (see para. 48); wherein the second portion extends between the upper surface and the first portion; wherein the second portion extends substantially perpendicular to the upper surface and the first portion extends obliquely relative to the upper surface; and wherein the first portion extends at an acute angle relative to the upper surface (see figs 12a and 12b and para. 57), in order to provide a projection that resists extrusion from a vertebral body (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the implant of Kohrs to include shape memory alloys and second and fourth portions in view of Ferree, in order to provide a projection that resists extrusion from a vertebral body. Kohrs teaches, as for claim 84, wherein the first material and the second material are substantially identical.

It is noted, as for claims 85-87, that Ferree teaches wherein at least one of the first and second shape memory alloys comprise Nitinol or a copper-based alloy but

does not explicitly state a third material different than the second material. It would have been obvious to one of ordinary skill in the art at the time of the invention to use different shape memory alloys, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

As for claims 103-121, it is noted that the combination of Kohrs in view of Ferree teaches the claimed invention including two upper projections and two lower projections (see Kohrs fig. 2).

As for claim 122, it is noted that the combination of Kohrs in view of Ferree teaches the claimed invention, except for explicitly stating that there are nine pillars. It is noted that it would have been obvious to one of ordinary skill in the art to modify the implant of Kohrs in view of Ferree to include nine pillars, since it has been held that a mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). See also MPEP 2144.04(VI)(B).

As for claim 100, the combination of Kohrs in view of Ferree teaches the claimed implant except for wherein the plurality of pillars comprises eight pillars proximate the perimeters of the upper and lower shells and one pillar interiorly offset from the perimeters of the upper and lower shells. As for the plurality of pillars contains eight pillars, it is noted that it has been held that a mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). See also MPEP 2144.04(VI)(B). Kohrs further

teaches a pillar interiorly offset from the perimeters of the upper and lower shells (see fig. 2 and note pillar 22+24+26+28 and note that said structure is also located in the center of the implant near ref. 36), in order to provide better support to the implant (see abstract and fig. 2).

Response to Arguments

Applicant's arguments with respect to claims 76-122 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARA R. GEORGE whose telephone number is (571)272-3402. The examiner can normally be reached on M-F from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tara R George/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733